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Food and Agricultural Import Regulations and Standards

Country Report

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Report Highlights:

Romania is adopting the European legislation a very fast pace as the European integration is approaching. Major part of the newly adopted legislation has already been implemented. Legislation on food additives, food flavors, pesticides and residues, food contaminants, organic products and biotech products was amended during 2005. The report presents also the major regulations affecting products of animal origin. Import procedure has been slightly amended especially regarding the importer's obligations. Unless specified otherwise, the regulations were enforced at the moment of publication.

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DISCLAIMER:

This report has been prepared by the Office of Agricultural Affairs of the USDA/Foreign Agricultural Service in Bucharest, Romania for U.S. exporters of domestic food and agricultural products. While every possible care has been taken in the preparation of this report, information provided may not be completely accurate either because policies have changed since its preparation, or because clear and consistent information about these policies were not available. It is highly recommended that U.S. exporters verify the full set of import requirements with their foreign customers, who are normally best equipped to research such matters with local authorities, before any goods are shipped. FINAL IMPORT APPROVAL OF ANY PRODUCT IS SUBJECT TO THE IMPORTING COUNTRY'S RULES AND REGULATIONS AS INTERPRETED BY BORDER OFFICIALS AT THE TIME OF PRODUCT ENTRY.

Please contact this office, if you would like further information about the material contained in this report. Our telephone, fax, and e-mail address are provided at the end of this report.

SECTION I. FOOD LAWS

Several Government agencies and ministries in Romania have responsibilities related to agri-food safety and quality as well as food importation. Most of the relevant norms and regulations were harmonized with the European Union (EU) legislation. Currently, the process of transposing EU regulations into domestic legislation is being accelerated, as the authorities are determined to move faster towards country's European accession, scheduled for 2007. Some of the regulations will be enforced at the moment of accession, while others will be enforced prior to this moment.

The most relevant provisions are set out within the following general framework:

- Veterinary Order 148/2005 regarding the surveillance, prevention and control of animal diseases, the ones transmissible to humans, animal protection and environment protection
- Government Ordinance 42/2004 regarding the organization of veterinary activity
- Government Emergency Ordinance 97/2001 regarding food production, distribution and commercialization, with the latest amendment Order 551/2004 regarding standard methods for analysis of alcoholic drinks
- Law 214/2002 amending Government (GOR) Ordinance 49/2000 on obtaining, testing, utilization, and commercialization of genetically modified organisms (GMOs), as well as products derived from GMOs.
- Law 244/2002 on wine and vine-yards with the latest amendment through Minister of Agriculture Order 645/2005 on including the Romanian vineyard regions in the European Union regions.
- Government Decision 1020/2005 providing technical norms for natural mineral water exploitation and commercialization.

These pieces of legislation are jointly proposed and/or endorsed by the GOR agencies with competency in protecting consumers and lay down conditions and requirements regarding food quality all along the marketing chain.

The Ministry of Agriculture, Forests and Rural Development

The Ministry of Agriculture, Forests and Rural Development (MAFRD) is the specialized body of the central public administration being under governmental jurisdiction. It applies the Government's strategy in the field of agriculture, food processing, as well as rural development and forests.

Under the Ministry of Agriculture, Forests and Rural Development the following agencies participate in the regulation of the agri-food market:

- The Testing and Control Lab for Seeding Material Quality
- The State Institute for Plant Varieties Testing and Registration
- The National Office for Wines
- The National Agency for Livestock Breed Amelioration and Reproduction (ANARZ)
- The Agency Land Reclamation
- The National Company for Fishery Fund Administration
- National Forestry Authority

Further information on the main activities of the Ministry of Agriculture, Forests and Rural Development can be viewed at www.maap.ro

The Ministry of Environment and Waters Management (MEWM)

Ministry of Environment and Waters Management is the main body conducting environmental risk assessment (including for GMOs) and monitoring activities that might harm human health and the environment.

More information regarding the activities of Ministry of Environment and Waters Management can be found at: <http://www.mmediu.ro>

The Veterinary and Food Safety National Authority (VFSNA)

The institution was established in January 2004 and it is the main body for sanitary-veterinary and food-safety activities. Before that moment, the Veterinary Agency was subordinated to Ministry of Agriculture.

Currently, the Agency performs activities related to animal health and foodstuffs of animal origin, as well as food safety. Its activity was significantly broadened to all aspects generally encompassed by food safety regulating and monitoring.

VFSNA organizes and coordinates all sanitary-veterinary activities, elaborates national norms and regulations, including the use of animal medical drugs. It is responsible for negotiating health certificates with international veterinary authorities for animals and products of animal origin for Romanian imports, in order to ensure conformity with the national veterinary requirements. It issues health certificates for live animals and livestock products exported from Romania. VFSNA is responsible for monitoring and controlling the animal health status nation-wide.

Other ministries and Governmental bodies involved in the regulation of the agri-food market are:

The Ministry of Health (MH)

The Ministry of Health is responsible for overseeing the production and registration of drugs, food additives, and medical equipments. It is also responsible for the public health as it relates to food and contaminants.

Thus, prior to begin operations, food processing Romanian firms and multinational companies established in Romania must obtain the approval of the Ministry of Health, which has competency in authorizing and controlling the activity of the companies involved in food production, processing and distribution.

The Public Health General Directorate and the State Sanitary Inspection within the Ministry of Health are responsible for food safety and public health.

The official website of the Romanian Ministry of Health is: www.ms.ro

The National Authority for Consumers Protection (NACP)

The National Authority for Consumers Protection is a Government agency established with the aim of protecting the consumers' rights and interests. Its activity is performed within the framework given by the GOR Decision 755/2003.

NACP is actively involved in proposing, endorsing and promoting legislation related to consumer protection, including food products. However, starting with October 2005, this

Authority involvement in food safety has been limited and the institution is no longer responsible for food products manufacturers and sanitary-veterinary inspections.

More information about the National Authority for Consumer Protection can be found at the following web site: www.anpc.ro

SECTION II. LABELING REQUIREMENTS

The following authorities are responsible for regulating and enforcing labeling requirements in Romania at various stages of food chain:

- The Ministry of Agriculture, Forests and Rural Development
- The Ministry of Health
- The National Authority for Consumer Protection
- The Veterinary and Food Safety National Authority

A. General Requirements

The methodology and requirements for food labeling are set out in the GOR Decision 106/February 2002 - further detailed in its accompanying Methodological Norm 7/2002. GOR Decisions 5111/2004 and 1719/2004 amended the decision no. 106 though.

At the border inspection point, products of animal origin, subject to control should bear labels in Romanian language OR in a widely circulating language (except the name of the country which should be specified in Romanian). Every package should bear a label with the following information:

- the country of origin (in Romanian language)
- the name of the establishment;
- name of the product;
- date of production and date of expiration;
- storage temperature;
- list of ingredients, for processed products only.

The Romanian authorities will not accept any inconsistency between the establishment number or the shelf life written in the export documents and the ones written on the labels.

Romanian authorities do not accept labels transfer from one establishment to another even if such establishments belong to the same producer and are officially inspected by the FSIS authorities.

All the information written on the certificates and the labels must be comprehensible and clear, with no traces of change. All U.S. exporters are advised to ask the importer about special requirements regarding labeling of goods they intend to export.

In the case of prepackaged frozen products, the labels should mention that "re-freezing after defrosting is prohibited". This statement may be written directly on the packages or on "stick-on" labels.

Therefore, labels in Romanian language are not an import condition. However, all food products when reaching the retail chain or food service, imported or domestically produced, should bear labels containing the following compulsory specifications in Romanian language:

- the name of the product;
- the ingredient* list (for processed products only). These ingredients must correspond to the ones specified in the technical description of the product. The ingredients must

be presented in descending order as a percentage of the total weight of the product. The vitamins and minerals must be also mentioned in the list;

- the net content (weight/capacity);
- the expiration date (best before, or expires onfor perishable products);
- the required storage conditions (temperature, humidity, etc.), when applicable;
- the name and address of the producer/packer/ distributor/ importer;
- place of origin or provenance if its absence would mislead consumers;
- usage instructions, in case the absence might result in improper usage;
- information meant to help the lot identification, which has to correspond with the number written in the export documents;
- date of manufacturing.

*Ingredients must be specified if they belong to the following categories: colorants, preservatives, antioxidants, emulsifiers, gels, stabilizers, aroma (flavorings), acidity correctors, modified potato starch, sweeteners antifoam, melting salt.

The Romanian labels costs are usually born by the Romanian importers/distributors. They can either attach the labels upon goods importation or have the exporters/packers do this operation before the goods depart United States.

In case of alcoholic drinks with alcoholic concentration higher than 1.2% vol., the list of ingredients should observe specific legislation, for instance Law of Wine and Vineyards no. 244/2002 and Minister of Agriculture regarding 268/2003 regarding definition, description and presentation of alcoholic drinks.

It is prohibited to use pictures of fruits/vegetables, parts of them or other ingredients on labels, presentation packaging, catalogues and advertisements if they are not part of the name under which the products are sold and are not included in the list of ingredients. The same recommendation should be observed in the case only fruit flavors are used.

In case of ready-to-drink products which contain caffeine in a proportion larger than 150 mg/l, the expression "high content of caffeine" should be placed on the label, right under the name of the product. The above specification does not apply to products such as coffee, tea, coffee extract and tea extract which are sold under the name "tea" or "coffee".

It is forbidden to use label specifications that refer to potential effects on human health, such as: energizer, fortifier, tonic or refresher.

Below there are described supplementary labeling requirements for a selection of food products:

1. Dairy products:
 - labeling must specify the fat content, in percent terms;
 - for the pasteurized milk the following specification is required: "Store at temperatures of 2-4 degree C";
 - the processing technology (pasteurized/UHT sterilized);
 - the dry matter content for powdered milk;
 - nutritional data for dietetic and dairy food products (energetic value, proteins, glucose, fats, fatty acids, fiber and sodium) as well as the added flavorings.
2. Margarine
 - margarine type;
 - fat content in percentage, content of added milk, butter, vitamins etc.;
 - margarine containing over 0.5% salt should be labeled as "salted".

3. Meat and products derived from meat. The label must specify:
 - the animal specie the meat comes from;
 - the processing technology/treatment used (salted, smoked, boiled, refrigerated, frozen, sterilized);
 - for meat products, the type of casing (natural or collagen membrane, edible or non-edible).

4. Eggs and egg products
 When shelving the product a label should be attached mentioning:
 - fresh big eggs (weight > 50 grams/egg) or
 - fresh small eggs (weight between 40-50 grams/egg).
 - for egg products, the egg content should be expressed in percentage, as well as the storage temperature
 - the expiration date should be stamped on each piece of egg.

5. Vegetables and fruits: the date of freezing, if applicable.

6. Natural juices: the minimum fruit content (in percent terms); if obtained from concentrate, this will be specified on the label, as well as whether the juice is with or without fruit pulp.

7. Fruits, vegetables and mushrooms: if they are not predominant and are used in variable proportions, they should be listed on the label after the expression "in variable proportions".

8. Chocolate and chocolate products
 - cocoa content in dry substance "cocoa...% min."
 - in the case of filled chocolate, the type of filling should be specified
 - if chocolate products contain more than 1% coffee or alcoholic drinks, their levels should be included in the labels

9. Beef labeling
 Beef and beef products labeling in correlation with cattle identification and recording is regulated by Order of Ministry of Agriculture 345/2002, which has been recently amended through Order 115/2005. The provisions referring to labeling will be enforced on January 1, 2007. According to this regulation, the label must contain the following information:
 - reference code, which insures the link between meat and the animal where the meat originates from
 - approval no. of the establishment where the animal was slaughtered; the label should contain the expression: "slaughtered in (name of the country), approval number"
 - approval no. of the cutting plant; the label should contain the expression: "cut in..... (name of the country),..... approval number".

B. Biotechnology Labeling

According to Law 214/2002, the producer is responsible for labeling biotech products placed on the market. The label shall clearly state if the genetically modified organism is present. The label bearing the inscription "This product contains genetically modified organisms" is compulsory. There is currently no law or regulation governing the use of labels such as biotech-free, non-biotech, GMO-free, or non-GMO. Law 214/2002 states that within a period of 10 years procedures for such labeling will be established.

The GOR Decision 106/2002 - further detailed in its accompanying Methodological Norm 7/2002 - provides more details on the labeling methodology of foods obtained from

biotechnology or containing genetically modified additives derived from GMOs. This norm is narrowed to foodstuffs delivered as such to the final consumer and to processed food entirely or partially obtained from: (i) genetically modified soybean and/or (ii) genetically modified corn. "Product derived from GM Soybean" or "product derived from GM corn" must be clearly written on the label. These additional labeling requirements can be ignored if the content of biotech soybean or corn is less than 1 percent of total ingredients.

C. Organic Labeling

Imported products should be labeled as "organic" if they were produced by organic methods confirmed by the certificate of compliance. According to GOR Ordinance 34/2000, the product label must contain: the name and the address of the producer/processor, the name of the product and the ecological production method, the name and the mark of the inspecting and certifying institution, the storage conditions, the minimum term of validity, the interdiction to store the ecological products along with ordinary products. The labels should also contain a special stamp for organic products registered at the State Office for Inventions and Patents (OSIM), which certifies the product complies with organic production rules.

D. Nutritional Labeling

The GOR Decision 106/2002, Annex 2, regulates nutritional foodstuff labelling. The regulation concerns nutritional labelling for food products to be delivered to the ultimate consumer. It shall also apply to foodstuffs intended for supply to restaurants, hospitals, canteens and other similar public caterers. The provisions of this regulation shall not apply to:

- a) natural mineral waters or other waters intended for human consumption,
- b) diet integrators/food supplements.

Nutritional labeling shall be optional. Nutritional labeling shall be compulsory when a nutrition claim appears on label, in presentation or in advertising.

The only nutrition claims permitted shall be those relating to energy, to certain nutrients (proteins, fat lipid, fiber, sodium, vitamins, minerals etc.) and to substances which belong to or which are components of a category of those nutrients.

The information provided to consumers, regarding the nutritional labeling consist of either group 1 or group 2 in the following order:

Group 1: (a) energy value; (b) the amounts of protein, carbohydrate and fat.

Group 2: (a) energy value; (b) the amounts of protein, carbohydrate, sugars, fat, saturates, fiber and sodium.

Where a nutrition claim is made for sugars, saturates, fiber or sodium, the information to be given shall consist of group 2.

Nutritional labeling may also include the amounts of one or more of the following: starch, polyols, mono-unsaturated and poly-unsaturated fatty acids, cholesterol or any of the minerals or vitamins included in the food products in a significant amount.

The declaration of substances which belong to or are components of one of the categories of nutrients referred above shall be compulsory when a nutritional claim is made.

The energy value and nutrients proportions or their components shall be numerical. The units of measure to be used are the following:

- a) energy - kJ and kcal;
- b) protein - grams (g);

- c) carbohydrate - grams (g);
- d) fat lipids - grams (g);
- e) fiber - grams (g);
- f) sodium - grams (g);
- g) cholesterol - milligrams (mg);
- h) vitamins and minerals - the units specified in the table.

Information shall be expressed per 100 g or per 100 ml or per serving or per portion, provided that the number of portions contained in the package is specified on the label. Information on vitamins and minerals must be expressed also as a percentage of the recommended daily intake RDI.

All provisions concerning nutritional labeling shall apply to retail and bulk food offered for sale to final consumers or to caterers, as well as to foodstuffs packaged at the point of sale or pre-packed for immediate sale.

The information on labels shall be expressed in such a way to be easily understood by purchasers. This information shall be printed in Romanian language, regardless the country of origin, and shall not prevent such information being indicated in more than one language.

SECTION III. PACKING AND CONTAINER REQUIREMENTS

Packing and container requirements in Romania do not differ from general international standards. However, plants for cultivation and propagating material of U.S. origin are approved for importation and transport in Romania assuming they are packed in special packages, sealed and with the original labels on which the identity, quality, species, variety, biological category and batch number are specified.

SECTION IV. FOOD ADDITIVE REGULATIONS

A. Food additives

Ministry of Health, Ministry of Agriculture (Department of Food Industry, Standards, Marks and Licenses) together with the Veterinary and Food Safety Authority are the authorities responsible for the regulating food additives in foodstuffs. Order 438/295/2002 defining and listing additives permitted for use in foodstuffs was modified through Order 154/2005, entering into force on June 6, 2006. The main changes refer to lists of products in which sweeteners can be added, new food additives and new dose levels for several food products.

B. Flavors

Order 565/2005 issued by Min. of Agriculture jointly with Ministry of Health and the Veterinary and Food Safety Authority concerning flavorings used or intended for use in or on foods amended Order 83/2002 on the same topic, enforced in January 2006. The main changes refer to smoke flavorings and the procedure to introduce on the market smoke flavorings or products on or in which such flavorings have been used. Some of the provisions of this regulation will be enforced when Romania will become part of the European Union.

SECTION V. PESTICIDE AND OTHER CONTAMINANTS

A. Pesticides

Generally, Romania adopts the international standards (Codex Alimentarius) on tolerance of pesticides, herbicides and fungicides used against crop diseases and pests. The authority

responsible for the registration of agricultural chemicals is the General Directorate for Environmental Protection within the Ministry of Environment and Waters Management, from where the U.S. exporters can obtain a list of approved pesticides.

B. Pesticides and substances residues

Order 147/2004 issued by the Veterinary and Food Safety Authority and amended later through Order 82/2005 establishes the maximum levels of pesticide residues accepted in products of animal origin.

The Veterinary Order 54/2005 transposes the EU regulation 2005/34/CE laying down the harmonized standards for testing on certain residues in products of animal origin imported from United States, as well as measures applied to shipments not conform with EU legislation. According to this regulation, where results of analytical tests are at or above the minimum required performance limits (MRPLs) set by the Veterinary Order 51/2005 (transposing Decision 2002/657/EC), the consignment concerned will be treated as non-compliant with the Romanian legislation.

Until October 1, 2006, when EC Rule 882/2004 will be enforced, the Romanian competent authorities will detain the non-conform shipments and having heard the food business operators, will take the following measures:

- a) order that such consignments be destroyed or re-dispatched outside Romania;

The competent authorities shall allow re-dispatch of consignments only if:

- the destination has been agreed with the feed or food business operator responsible for the consignment; and
- the food business operator has first informed the competent authority of the third country of origin or third country of destination (if different), about the reasons and circumstances preventing the placing on the Romanian market the consignments concerned; and
- when the third country of destination is not the third country of origin, the competent authority of the third country of destination has notified the competent authority of its preparedness to accept the consignments.

- b) if the consignments have already been placed on the market, recall the consignments before taking one of the measures referred to above.

The re-dispatch should take place no more than 60 days after the day on which the competent authority decided on the destination of the consignment, unless legal action has been undertaken. If, after the expiry of the 60-day period, re-dispatch does not take place, the consignment shall be destroyed, unless the competent authority is satisfied that a delay is justified.

When the results of analytical tests on products are below the MRPLs set by the Veterinary Order 51/2005, the products will not be prohibited from entering the food chain.

The feed or food business operator responsible for the shipment or its representative is responsible for the costs incurred by competent authorities when applying this Order.

The maximum levels of pesticide residues in plants and vegetal products are laid down in Order 505/2005 issued by Ministry of Agriculture. The regulation includes a list of products of plant origin and the accepted maximum levels of pesticide residues for each of them. Products detected with residues above those limits are not accepted in the food chain.

The Veterinary Order 82/2005 establishes the measures for surveillance and control of certain substances and their residues in live animals and their products, as well as residues of veterinary medicines in products of animal origin. This regulation refers to administration of substances having anabolic effect and unauthorized substances (stilbenes, stilbene derivatives, and their salt and esters, antithyroid agents, steroids, resorcylic acid lactones including zeranol, beta-agonists etc.), various veterinary drugs and contaminants (antimicrobial substances, anthelmintics, anticoccidials, including nitroimidazoles, carbamates and pyrethroids, sedatives, non-steroidal anti-inflammatory drugs, other pharmacologically active substances, organochlorine compounds including PCB, organophosphorus compounds, chemical elements, mycotoxins, dyes, other substances).

In the case, the control on imported live animals, products of animal origin and feed leads to the conclusion that unauthorized products and substances have been administered to animals, the veterinary authority will take the following measures:

- inform United States about the nature of the products and the batch concerned;
- strengthen the control on all animals or products from the same source;
- in the case the consequent controls reveal the presence of the unauthorized products and substances or of residues of such substances or products:

(i) the batch or the part of the batch concerned must be returned to United States at the expense of the consignor or his representative, specifying on the certificate the reasons for rejecting the batch;

(ii) depending on the nature of the infringement found and the risk associated with such an infringement, it must be left to the consignor to decide whether to send back the batch or part of the batch concerned, to destroy it or to use it for other purposes authorized by legislation, without indemnity or compensation;

C. Food contaminants

The main regulation on food contaminants is Order 97/2005 issued by the Veterinary Authority, transposing the UE legislation on certain contaminants from food of animal and non-animal origin. The regulation sets the maximum contaminants levels that could be detected in both animal and non-animal products.

Maximum contaminants limits are also applied to food for babies and young children. However, in case of products under drying and dilution treatment or processing, possible modifications in the contaminants levels and relative ingredients concentration will be considered when setting up the upper limits.

Below, the maximum accepted levels of main contaminants for certain food products are shown.

Nitrates

Product	Maximum level (mg NO ₃ / kg)
Food for babies and young children	200

Note: The maximum level applies to ready-to-eat products or as they are consumed according to the producers suggestion.

Mycotoxins

Aflatoxins

Product	Maximum level (µg / kg)		
	B1	(B1+B2+G1+G2)	M1

Ground nuts, nuts and dried fruits, of which:			
- Ground nuts, nuts and dried fruits and their processed products, intended for human consumption or as an ingredient in foodstuffs	2.0	4.0	-
Groundnuts subject to sorting or other physical treatment, before human consumption or use as a food ingredient	8.0	15.0	-
Nuts and dried fruits subject to sorting or other physical treatment, before human consumption or use as a food ingredient	5.0	10.0	-
Cereals			
Cereals and their processed products for direct human consumption or use as a food ingredient	2.0	4.0	-
Cereals (except corn) subject to sorting other physical treatment, before human consumption or use as a food ingredient	2.0	4.0	
Corn subject to sorting other physical treatment, before human consumption or use as a food ingredient	5.0	10.0	
Milk	-	-	0.05
Food based on processed cereals for babies and young children	0.10	-	-
Infant formulae and follow-on formulae including milk for infants and follow-on	-	-	0.025
Food with special nutritional destination, especially for infants	0.10	-	0.025

Ochratoxin A

Product	Maximum level ($\mu\text{g} / \text{kg}$ or ppb)
Cereals and derivative products	
-- Raw cereals	5.0
-- All products derived from cereals	3.0
Dried grapes (sultana)	10.0
Wine	2.0
Food based on processed cereals for babies and young children	0.50
Food with special nutritional destination, especially for infants	0.50

Patulin

Product	Maximum level ($\mu\text{g} / \text{kg}$ or ppb)
Fruit juices and concentrated fruit juices	50.0
Distilled spirits, cider and other fermented drinks made from apples or containing apple juice	50.0
Apple products	25.0
Apple juice	10.0

Maximum levels are also set for other mycotoxins, such as DON, zearalenon, fumonisin, toxins T-2 and HT-2.

Heavy metals

Lead (Pb)

Product	Maximum level (mg / kg humid mass)
Infant formulae and follow-on formulae	0.02
Meat of bovine, sheep, pig and poultry	0.1
--- offals from bovine, sheep, pig and poultry	0.5
Muscle fish meat	0.2
Muscle meat of common two-banded seabream (<i>Diplodus vulgaris</i>), eel (<i>Anguilla anguilla</i>), grey mullet (<i>Mugil labrosus labrosus</i>), grunt (<i>Pomadasy benneti</i>), mackerel (<i>Trachurus species</i>), sardine (<i>Sardina pilchardus</i>), sardines (<i>Sardinops species</i>), spotted seabass (<i>Dicentrarchus punctatus</i>), or wedge sole (<i>Dicologlossa cuneata</i>)	0.4
Crustaceans, excluding brown meat of crab	0.5
Bivalve mollusks	1.5
Cephalopods (without viscera)	1.0
Cereals, legumes and pulses	0.2
Fats and oils, including milk fat	0.1
Fruit juices, concentrated fruit juices and fruit nectars	0.05
Wines	0.2

Cadmium (Cd)

Product	Maximum level (mg / kg humid mass)
Meat of bovine, sheep, pig and poultry	0.05
Liver of cattle, sheep, pig and poultry	0.2
Kidney of cattle, sheep, pig and poultry	1.0
Muscle fish meat	0.05
Crustaceans, excluding crab brown meat	0.5
Bivalve mollusks	1.0
Cephalopods (without viscera)	1.0
Cereals	0.1
Soybeans	0.2

3-monochloropropane-1,2-diol (3-MCPD)

Product	Maximum level (mg / kg)
Hydrolysed vegetable proteins	0.02
Soy sauce	0.02

The regulation sets further maximum levels also for other contaminants in food such as Dioxine, PCDFs, Staniu and aromatic policiclic hydrocarburs.

The Veterinary Order 120/2005 (transposing EC 2002/32) lays down the maximum levels of undesired substances that can be detected in animal feeding stuff, such as Arsen, lead, mercury, nitrites, cadmiu, aflatoxin B1 etc.

All regulations on pesticides residues and undesired substances are equally applied to domestic and imported products.

SECTION VI. OTHER REGULATIONS AND REQUIREMENTS

The phytosanitary legal framework has little changed over the last two years. GOR Ordinance 136/2000 (approved through Law 214/2001) and GOR Decision 1030/2001 (changed by GOR Decision 1619/2003) are the main legal provisions in this field. The methodological norms of the latest provide a full list of organisms considered harmful on the Romanian territory and which are forbidden for importation. Also, agricultural products contaminated with the specified organisms are forbidden for importation.

Every year Ministry of Agriculture updates the Official Catalogue of registered varieties of plants for cultivation in Romania (Order 727/2005), which includes all varieties tested by the State Institute for Varieties Testing and Registration. The following set of information is published for each variety: name, owner, registration year, re-registration date (year) or de-listing date (year), comments. Crop, vegetable and ornamental plant varieties are kept in the Official catalogue for 10 years, and 15 years in case of fruit trees, vineyard and ornamental shrubs. Two years before this period expires, a request for re-registration along with the necessary seeds for testing should be submitted to the appropriate authority.

U.S. suppliers is important to note that only plant varieties for cultivation (seeds and propagating material) included in the Romanian Official Register, or in the EU Official Catalogue or in the Official Catalogue of one of the Member States will be accepted for importation in Romania. The importer wishing to import one plant variety should request an Import permit, along with documents proving that the plant variety has been already registered/introduced in EU official plant register or one of the Member States.

Order 257/2002 issued by Ministry of Agriculture regulates import of seeds and propagating material for multiplication and cultivation. Phyto-sanitary certificate issued by APHIS for certain plant species listed in Annex 5 of GOR Decision 1030/2001 and the import approval are the main documents necessary for importation.

The phytosanitary certificate, issued by USDA/APHIS, must accompany the products imported from the United States, certifying that the product is free of quarantine organisms. The import approval is issued by Ministry of Agriculture, based on the following documents submitted by the importer and it is 6 months valid:

- Import request (two copies of it submitted at least 10 days the actual import)
- Authorization for production, processing or marketing seeds and propagating material
- Import contract or similar document
- Other documents.

□ Medicinal and aromatics plants

Order 244/2005 issued by the Ministry of Agriculture along with Ministry of Health provides technical norm related to the production, processing and marketing of medicinal and

aromatics plants, used as they are, partially processed or processed as pre-dosed food supplements. List of plants forbidden to be used in any form as food supplements is part of the Order. It is prohibited to produce, exhibit or market as components of food supplements mushroom species outside the ones listed in Annex 2 of the Order (which includes edible mushrooms) or any derivatives of these mushrooms, or mushrooms cut in such a way that their variety cannot be identified etc.

It is forbidden to manufacture or market products which are not listed in Annex 2 or 3 (used as they are, partially processed or processed as food supplements under pre-dosed form), unless the Institute for Food Bio-resources has been notified. The notifying dossier should include the following information:

- the nature of product
- ingredients list (amount and value)
- nutritional analysis of the product, active substances, toxicity and stability
- product labeling
- commitment to make frequent product analysis and submit the results to the Institute for Food Bio-resources.

❑ **Wood Packaging Materials**

Ministry of Agriculture, Forests and Rural Development (Phytosanitary Department) transposed into the national legislation the new International Standards Phytosanitary Measures (ISPMs) on wood packaging materials (WPM), issued by the International Plant Protection Convention (IPPC), part of the United Nations Food and Agriculture Organization.

This standard describes phytosanitary measures to reduce the risk of introduction and/or spread of quarantine pests associated with wood packaging material. The new standard, known as ISPM15, intends to reduce the risk of introduction and/or spread of quarantine pests associated with wood packaging material.

Romania designed specific requirements and put in place a control system for implementing the new standards. Specific details have been also drawn up for the two treatments that can be applied to WPM, heat-treatment and fumigation with methyl bromide. Starting with January 2005, WPM exports take place according to the new standards. So far, there are no changes in requirements for WPM imports.

❑ **Fruits and vegetables**

Starting with May 2006, fruits and vegetables coming from United States have to comply with the minimum requirements on food safety, food hygiene, quality and product identification, packaging, labeling, stamps, storage and transportation provided by Ministerial Orders no. 770-781/2004, 871-881/2004, 969-979/2004. The following products are affected:

- a) **canned:** apricots, re-hydrated peas, green peas, green pods, plums, pine-apple, raspberry, fruit mix, asparagus, strawberries, pears, peaches, sugar corn, mandarins.
- b) **dry:** peaches, mushrooms, sultana, root vegetables, apples, onion,
- c) **frozen:** Broccoli, green peas, peaches, raspberry, strawberry, carrots, corn, cauliflower, Brussels cabbage, green pods, spinach, fried potatoes, cranberries.
- d) **preserved:** mashed apples.

In general, the above products should be processed and packaged in proper hygiene conditions. The raw materials should be fit for consumption, ripe and clean, with contaminants and pesticide residues below the maximum limits. The packages/cans which are in direct contact with the products should: be new, ensure the nutritional, physical and

chemical features of the products, protect the product against de-hydration and heat, protect the products from microbiological contamination or other.

SECTION VII. OTHER SPECIFIC STANDARDS

Veterinary regulations

The Veterinary Order no. 148/2005, in effect since January 2006, regulates the activities of surveillance, prevention and control of animal diseases, the ones transmissible to humans, animal protection and environment protection. This regulation provides for each disease a set of rules regarding surveillance, sample testing, risk areas, inspection frequency. Sanitary and veterinary surveillance in farms, food processing establishments, cold storages, and stores is also provided by this regulation.

Other regulations refer to poultry meat, live animals protection, animal by-products not intended for human consumption, biological reproduction material, fishery products.

□ Poultry Meat

The current version of the import certificate for poultry meat allowing all U.S. federally inspected plants to export to Romania will be valid until January 1, 2007. Afterwards the EU legislation will be fully implemented, which would mean no U.S. poultry shipments would be allowed in.

□ Live animals protection

Live animals protection during transportation is regulated by Order 119/2005 issued by the Veterinary Authority and in effect since November 2005. The regulation provides a set of rules regarding the feeding, comfort and resting for each animal species during transportation. The regulation applies equally to live bovine, ovine, sheep, hogs, birds, rabbits etc. imported and domestically produced animals. Import, transit, export and transport of live animals from United States on the Romanian territory will be authorized based on the shipper's written declaration that all provisions of the regulation are observed and a route chart is available.

□ Animal by-products not intended for human consumption

The legislation regarding collection, transportation, storage, handling, processing and use of animal by-products was fully harmonized with EU legislation through Order 723/2003 (transposing EC regulation 1774/2002) and it is in place since 2003. Thus, further processed products of U.S. origin, such as pet food (canned, dogchews, raw petfood, other type), game trophies (treated and untreated), hides and skins, have to be produced according to the above mentioned regulation. Consequently, only U.S. plants approved for EU exports will be eligible for export to Romania.

□ Livestock reproduction material

Order 342/2005 issued by the Ministry of Agriculture and implemented in May 2005, approves the technical norms for state inspection regarding the control on animal improvement and breeding. The State Inspection is part of the National Agency for animal improvement and breeding (ANARZ), within the Ministry of Agriculture and is responsible for all activities in the field of breeding, improvement and conservation of genetic fund as well as import and export of biologic breeding material and frozen semen.

The National Agency for Animal Improvement and Breeding (ANARZ) authorizes import of frozen semen of U.S. origin, under quantitative and qualitative aspects. Romanian importers have to obtain the above authorization before signing contracts with suppliers and with their beneficiaries.

The consignments should be accompanied by certificate of origin and certificate of productivity which prove the identity and the genetic value required by ANARZ.

Import requirements for frozen bovine semen imports described below are worthwhile for U.S. animal genetics exporters.

Veterinary Order 127/2004 establishes the sanitary and quality requirements for frozen bovine semen to be marketed on the Romanian market. According to this, the bovine semen, after defrosting, should comply with the following sanitary and quality requirements:

a) frozen semen in doses should be free from specific pathogen germs: *Brucella* sp., *Listeria monocytogenes*, *Leptospira interrogans*, *Actinomyces pyogenes*, *Campylobacter venerealis*, *Mycobacterium tuberculosis*, *Staphylococcus aureus*, *Streptococcus* (groups Lancefield A and D), *Escherichia coli*, *Pseudomonas aeruginosa*, *Bacillus* sp., *Corynebacterium* sp., *Salmonella* sp., *Serratia marcescens*, *Nocardia asteroides*, *Chlamydia psittaci*, *Mycoplasma bovis*, *Fusobacterium nucleatum* and other anaerobic germs;

b) the total number of germs should not exceed 5×10^3 /ml.

c) the frozen semen should be free from the viruses IBR-IPV, BVD-MD, fungi of types *Candida* sp, *Aspergillus* sp., *Rhizopus* sp., *Mucor* sp., *Absidia* sp. and the Protozoa *Tritrichomonas bovis*, *Toxoplasma gondi*, *Neospora* sp.

d) After thawing, the bull semen should present:

- minimum 30% mobility;
- a concentration of minimum 7.5 million useful spermatozoa per dose;
- spermatozoa with a normal morphology: over 70% of total spermatozoa number.

❑ Fishery Products

Seafood products to be exported to Romania require a bilingual (English/Romanian) certificate, issued by the Seafood Inspection Program of the U.S. Department of Commerce. However, as Romania adopts the EU legislation, it is very likely that during 2006, the import certificate would be changed. U.S. exporters are advised to contact the FAS office for updates or visit the FAS website (Attaché reports).

The Veterinary Order 100/2004 issued by the Veterinary Authority and in place since 2004 presents the supplementary requirements for control of fishery products, crustaceans, mollusks, gastropods and batrachians for final consumers or further processing. The regulation equally impacts domestic and import products.

The Veterinary inspection focuses on origin, processing conditions, transport, storage, sale and hygiene for fish and seafood in all stages: live, chilled, frozen. Chilled fish will be packed with crushed ice of less than 4 cm in size, in consecutive layers. Frozen fishery products over 3 kg weight will be individually packed, while for fish under 3 kg weight proper packaging in briquettes with appropriate labels attached. The following categories of products are not accepted to direct sale or further processing:

- fishery products initially live but which subsequently died in water;

- products stored in dirty or depreciated packaging which might be harmful for human health;
- products where the ice is not clean and non-transparent
- products which have been thawed and re-frozen
- products which have unclean surface, modified color and shape;
- products with mould.

In addition, mechanically recovered fish meat is forbidden for direct sales to final consumers. Furthermore, the regulation provides requirements for seafood sale, such as mollusks, crustaceans, gastropods and batrachians.

Until May 2005, whole fish with parasites forms on the viscera or muscles would have been prohibited from sale. The Veterinary Order 49/2005 amends this provision though. Thus, whole fish detected with parasites forms on the viscera and which can be completely removed, will be directed to processing, under sanitary and veterinary supervision, in an approved establishment equipped for such operations.

Whole fish, where parasites forms have been detected in muscles or in both viscera and muscles will be considered unfit for human consumption and prohibited from sale.

Organic Food

The Governmental Decision 34 of April 2000 sets out standards for production, classification, processing, packaging, importation, distribution, and organic products certification.

In 2001, the National Authority for Ecological Products (ANPE) was established within the Ministry of Agriculture. According to the rules for inspection and certification of organic products approved in 2003, all companies which produce, process, transport, import or export organic products have to be registered at ANPE and be subject to inspection performed by a certified institution for inspection and certification.

Import and export rules are provided by Order 721/2003 issued by the Ministry of Agriculture. In order to import U.S. organic products, Romanian importers must demonstrate ANPE that the products were obtained according to standards equivalent to the Romanian standards and were subject to an equivalent control.

The Border inspection office will check the correspondence between the data included in the certificate of inspection and the data written on the packages and labels.

Upon receiving the certificates of control issued by the competent authority in the exporting country, the importer will submit to the inspection and certifying institution the following information:

- name and address of the first beneficiary
- a copy of the certificate of control
- other relevant information, if requested.

Organic products are accepted for importation if they are properly packed. The packages or containers should be closed and sealed, with the exporter's name specified, so that products replacement is avoided.

Products derived from Biotechnology

The main piece of legislation regulating Biotechnology in Romania, Law 214 of April 19, 2002, effective from May 2002, amending GOR Ordinance 49/2000 on obtaining, testing, utilization, and commercialization of GMOs, as well as products derived from GMOs is still in

place. However it has been amended through Order 606/2005 of Ministry of Environment approving the format for presentation of results for releasing GMO plants for other purposes than commercialization. The second piece of legislation amending Law 214/2002 is Order 838/2005 of Ministry of Environment regarding the implementation of the Annex 12.2 "Monitoring Plan".

Two other pieces of legislation relevant to biotech-related issues, GOR Decision 106/February 2002 on labeling food derived from GMOs or containing genetically modified additives or derived from GMOs and Order 462/2003 issued by Minister of Agriculture, Forests and Rural Development with provisions for tracing biotech products are still valid.

In addition, Ministry of Environment approved Order 923/2005 (transposing Directive 2001/18/EC) laying down the summary notification regarding placing on the market the genetically modified organisms as or in products.

The summary notification should be completed and submitted by the notifier to the Ministry of Environment, in both hard and electronic copies, in Romanian and English languages.

First part of the summary notification applies to products consisting of or containing genetically modified organisms other than "higher plants" and contains the following sections:

- A. General Information
- B. Nature of the GMOs contained in the product
- C. Predicted behavior of the product
- D. Information related to previous releases
- E. Information related to the monitoring plan

The second part applies to products consisting of or containing genetically modified "higher plants". The term 'higher plants' means plants which belong to the taxonomic group Gymnospermae and Angiospermae. It contains the following sections:

- A. General Information
- B. Nature of the GMHP contained in the product
- C. Information related to previous releases
- D. Information related to the monitoring plan

Order 838/2005 issued by the Ministry of Environment describes the Monitoring Plan, which is part of the notification dossier and includes three sections:

- Monitoring strategy
- Monitoring Methodology
- Assessment, reporting, reassessment.

The purpose of the monitoring strategy is to detect the potential risks that may appear as a result of introduction of GMO on the market, the extent in which they need to be monitored, the appropriate approach and the period of monitoring activity.

Monitoring Methodology includes the parameters and elements that should be monitored as well as the monitoring methods, the main areas subject to monitoring and the frequency.

Assessment, reporting, reassessment section should determine the frequency of data examination and interpretation. Monitoring reports should be submitted by the notifier to the central authority for environment protection as well as other bodies, who will forward them to the EU Commission and other competent authorities. The notifier is responsible for ensuring transparency on the monitoring plan results through workshops, dissemination materials, webpage, scientific and commercial publications.

SECTION VIII. COPYRIGHT AND/OR TRADEMARK LAWS

The law provisions described in GAIN report 4003/2004 are still in place.

SECTION IX. IMPORT PROCEDURES

Romanian regulations require U.S. companies exporting products of animal origin to Romania to be inspected by the U.S. federal inspection service. Its Romanian counterpart is the Sanitary-Veterinary and Food Safety National Authority, which verifies whether import documentation complies with country's legislation. It also negotiates with the FSIS the type of certificate required for each product in accordance with the Romanian legislation.

The following documents are required for products of animal origin to be imported in Romania:

- Health Certificate for products intended for import to Romania (bilingual)
- Freezing Certificate issued by the producer, when applicable.
- Declaration of Conformity and / or Quality Certificate issued by the producer.
- Technical Description (especially for processed products).
- Certificate of origin (required by the Romanian Customs to calculate the applicable duty)

The Health Certificates for animal products, whether fit for human consumption or not, eligible for the Romanian market are posted on the FSIS website (www.fsis.usda.gov) or APHIS website (www.aphis.usda.gov).

The conditions and the sanitary veterinary procedure for import, export, and transit of live animals, products and by-products of animal origin, fodder and products of veterinary use are stated by Order 46/2005 issued by the Veterinary National Authority, which will be replaced by Order 138/2005 starting with February 1, 2006. Below the import requirements as provided in the new Order are presented.

In 2005, the import approval, which used to be issued by the Veterinary County offices at the importer's request, was discontinued. Starting with 2006, all importers have to register in an electronic database (TRAFFIC) and receive a general approval from the sanitary-veterinary county office. The importer has to inform the inspection border about shipments 24 hours before the estimated date of arrival. In this regard, the importer has to electronically submit the Common Veterinary Entry Document (DVCI) containing detailed information about the consignment.

Transit requirements are similar to the ones for import. Transit of goods will be accepted only if they originate from countries approved by the Romanian veterinary authority and which are not prohibited. If transit will imply unloading, stop or temporary storage on the Romanian territory, these operations can take no longer than 30 days from the date of entry. In case of products of animal origin, a certificate of non-manipulation issued by the veterinarian of the warehouse should accompany the products towards the importing country.

At the border, the goods are subject to documentary, identity and physical inspection. Furthermore, after arrival to their final destination (for instance warehouse) the goods are subject to documentary inspection, identity inspection, physical control or any other type of control to evaluate the food products safety.

The shipment leaving the border, has to reach its final destination in at most 72 hours, otherwise the importer's access to the TRAFFIC application will be denied.

In the case during the products inspection at the final destination, during transport or transit, the presence of pathogen micro-organisms or any cause that might be considered a major risk for animal or human health the veterinarians is detected, the veterinarian must inform the veterinary county office and the following actions are taken:

- detain the batch of products until further decision;
- declare the products unfit for human consumption;
- reprocess the products under sanitary-veterinary supervision so that their safety is insured;
- placing the re-processed products on the market assuming they comply with the micro-biological requirements;
- give the importer the possibility to use the products for other approved purposes, assuming the importer informs the competent authority in the country of origin;
- return the shipment to the country of origin, if that is accepted by the competent authority in that country;
- re-export to another country, if accepted by the competent authority in that country;
- destruction of the consignment, if the importer and the competent authority of the country of origin.

All costs incurred for products detention/stop, reprocess, return or destruction will be covered by the importer.

APPENDIX. GOVERNMENTAL REGULATORY AGENCY CONTACTS

The Ministry of Agriculture, Forests and Rural Development
24, Bd. Carol I, sector 3
Bucharest, Romania
Phone: 40 21 3072345
Fax: 40 21 3078635
Web site: <http://www.maap.ro>

The Ministry of Environment and Waters Management
12 Libertatii Blvd., Sector 5
Bucharest, Romania
Phone: 40 21 4100215
Fax.: 40 214100243
Website: <http://www.mmediu.ro>

The Ministry of Health
1-3, Cristian Popisteanu Str., sector 1, 010024
Bucharest, Romania
Phone: 40 21 3072500 or 40 21 3072600
Fax: 40 21 3141526
Web site: <http://www.ms.ro>

The National Sanitary-Veterinary and for Food Safety Authority
1B Negustori Street, sector 2
Bucharest, Romania
Phone: 40 21 3157875
Fax: 40 21 3124967
Website: <http://www.ansv.ro>

The National Authority for Consumers Protection
5 George Clemenceau St., Bucharest
Phone: 40 21 3121275
Fax: 40 21 3143462

Web site: www.anpc.ro

National Customs Authority

13 Matei Millo Street, Sector 1, Bucharest

Phone: 40 21 3155858; 40 21 3155859; 40 723565101; 40 723 565102; 40 723 565103

Fax: 40 21 313.82.51

Web site: www.customs.ro

National Agency for Improvement and Animal Breeding

59-63 Doctor Staicovici Street, Sector 5, Bucharest

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Web site: www.anarz.ro

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